



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

(Attorney Docket No.: 102286.408CON)

Applicant(s):

Collinge

Serial No.:

09/778,926

Filed:

February 6, 2001

For:

DIAGNOSIS OF SPONGIFORM ENCEPHALOPATHY

Group Art Unit:

1637

Examiner:

Riley, Jezia

Mail Stop AMENDMENT Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

CERTIFICATE UNDER 37 C.F.R. 1.8(a)

I hereby certify that this correspondence is being as first class mail in an envelope addressed to Mail Stop AMENDMENT, Commissioner for Patents, P.O. Box 1450, Mexandria, VA/22313, 1450 on the date set forth below.

12-29-2004

Date

INFORMATION DISCLOSURE STATEMENT

Commissioner:

Applicant and his attorney are aware of the following publications and information listed on the attached PTO Form 1449, and in accordance with 37 CFR §1.97(c) hereby submit these documents for the Examiner's consideration.

It is respectfully requested that the information above be expressly considered during the prosecution of this application and that the publications be made of record therein and appear among the "References Cited" on any patent to issue therefrom. In this regard, it is requested that the Examiner initial and return a copy of the enclosed Form PTO-1449 with the next Patent Office Communication.

This submission does not represent that a search has been carried out nor does it constitute an admission that the listed documents are material to the patentability of the invention, or that this enclosed art represents prior art. Applicant reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

01/05/2005 MBLANCO 00000002 080219 09778926

02 FC:1806

180.00 DA

Collinge U.S.S.N. 09/778,926

This Information Disclosure Statement is being filed before receipt of a final Office Action; therefore, the Commissioner is hereby authorized to charge the \$180.00 fee pursuant to 37 CFR §1.17(p) to Deposit Account No. 08-0219.

The Commissioner is also authorized to charge any fee deficiency or credit any overpayment to Deposit Account No. <u>08-0219</u>.

Respectfully submitted,

Date: <u>December</u> 29, 2004

Michael J. Twomey

Registration No. 38,349 Attorney for Applicant

Wilmer Cutler Pickering Hale and Dorr LLP 60 State Street

Boston, Massachusetts 02109

Tel: (617) 526-6190 Fax: (617) 526-5000

NFORMATION DISCLOSURE IN AN APPLICATION (Use several sheets if necessary)

OF

Docket Number 102286-408CON Application Number 09/778,926

Applicant Collinge

Filing Date 2/6/2001

Group Art Unit 1637

		U.S. Pate	ent Documents	
Examiner Initial	Document Number	Publn. Date mm-dd-yyyy	Name Of Patentee Or Applicant Of Cited Documents	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear

2

Foreign Patent Documents					
Examiner Initial	Cite No.	Foreign Patent Document Country Code-Number- Kind	Publn. Date mm-dd-yyyy	Country	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear
		WO 96/17249			
		GB 2 258 867			

Examiner's Initial		Other Documents (Including Author, Title, Date Pertinent Pages, Etc.)			
muca	A1	Baker, et al., "Aminoacid polymorphism in human prion protein and age at death in inherited prion disease," Lancet, Vol. 337, pp. 1286 (1991)			
	A2	Bessen, et al., "Biochemical and Physical Properties of the Prion Protein from Two Strains of the Transmissib Mink Encephalopathy Agent," J. Virol., 66(4):2096-2101 (1992)			
	АЗ	Bessen, et al., "Distinct PrP Properties Suggest the Molecular Basis of Strain Variation in Transmissible Mink Encephalopathy," J. Virol., 68(12):7859-7868 (1994)			
	A4	Bessen, et al., "Non-genetic propagation of strain-specific properties of scrapie prion protein," Nature, Vol. 375, pp. 698-700 (1995)			
	A 5	Brown, et al., ""Friendly fire" in medicine: hormones, homografts, and Creutzfeldt-Jakob disease," Lancet, Vol. 340, pp. 24-27 (1992)			
	A6	Brown, et al., "latrogenic Creutzfeldt-Jakob disease: An example of the interplay between ancient genes and modern medicine" Neurology, Vol. 44., pp. 291-293 (1994)			
	A7	Bruce, et al., "Transmission of bovine spongiform encephalopathy and scrapie to mice: strain variation and the species barrier," Phil. Trans. R. Soc. Lond. B, pp. 405-411 (1994)			
	A8	Bueler, et al., "Normal development and behaviour of mice lacking the neuronal cell-surface PrP protein," Nature, Vol. 356, pp. 577-582 (1992)			
	A9	Carlson, et al., "Linkage of Prion Protein and Scrapie Incubation Time Genes," Cell, Vol. 46, pp. 503-511 (1986)			
	A10	Caughey, et al., "The Scrapie-associated Form of PrP Is Made From a Cell Surface Precursor That Is Both Protease- and Phospholipase-sensitive," J. BioL. Chem., 266(27):18217-18223 (1991)			
	A11	Collinge, et al., "Genetic predisposition to latrogenic Creutzfeldt-Jakob disease," Lancet, Vol. 337., pp. 1441-1442 (1991)			
	A12	Collinge, et al., "Unaltered susceptibility to BSE in transgenic mice expressing human prion protein," Nature, Vol. 378, pp. 779-783 (1995)			
	A13	Collinge, et al., "Prion protein gene analysis in new variant cases of Creutzfeldt-Jakob disease," Lancet, Vol. 348, pp. 56 (1996)			
	A14	Collinge, et al., "Molecular analysis of prion strain variation and the aetiology of 'new variant' CJD," Nature, Vol. 383, pp. 685-690 (1996)			
	A15	Fraser, et al., "The lymphoreticular system in the pathogenesis of scrapie," in <u>Prion Diseases in Humans and Animals</u> , Eds. Prusiner, Collinge, Powell, and Anderton, pp. 308-317 (1992)			
	A16	Hecker, et al., "Replication of distinct scrapie prion isolates is region specific in brains of transgenic mice and			

EXAMINER DATE CONSIDERED

EXAMINER: Initial if citation is considered, whether or not citation is in conformance with MPEP § 609: Draw Line through citation if not conformance and not considered. Include copy with next communication to applicant.

Subt. For, PTO	RMATION	DISCLO	OSURE	Docket Number Application Number 102286-408CON 09/778,926 Applicant Collinge		
2 3005 W	(N AN APPL	LICAȚIO	NC			
	0 001014. 01100		2004.77	Filing Date	Group Art Unit	
Sheet	2	OF	2	2/6/2001	1637	

TRAD		
		hamsters" Genes & Development, Vol. 6, pp. 1213-1228 (1992)
	A17	Kascsak, et al., "Mouse Polyclonal and Monoclonal Antibody to Scrapie-Associated Fibril Proteins," J. Virol. 61(12):3688-3693 (1987)
	A18	Kimberlin, et al., "Incubation Periods in Six Models of Intraperitoneally Injected Scrapie Depend Mainly on the Dynamics of Agent Replication within the Nervous System and Not the Lymphoreticular System" J. Gen. Virol., Vol. 69, pp. 2953-2960 (1988)
	A19	Kimberlin, "The role of the spleen in the neuroinvasion of scrapie in mice," Virus Res., Vol. 12, pp. 201-211 (1989)
	A20	Kocisko, et al., "Cell-free formation of protease-resistant prion protein," Nature, Vol. 370, pp. 471-474 (1994)
	A21	Laemmli, "Cleavage of Structural Proteins during the Assembly of the Head of Bacteriophage T4," Nature, Vol. 227, pp. 680-685 (1970)
	A22	Lasmezas, et al., "BSE transmittion to macaques" Nature, (1996), Vol. 381, pp. 743-744
	A23	Marsh, et al., "Comparison of Scrapie and Transmissible Mink Encephalopathy in Hamsters. II. Clinical Signs, Pathology, and Pathogenesis," J. of Infectious Diesases, 131(2), pp. 104-110 (1975)
	A24	Masood, "Britain draws up 'superleague' plan for leading research universities," Page G, Nature, Vol. 382, pp. 381 (1996)
	A25	Palmer, et al., "Homozygous prion protein genotype predisposes to sporadic Creutzfeldt-Jakob disease," Nature, Vol. 352, pp. 340-342 (1991)
	A26	Palmer, et al., "Sequence Variation in Intron of Prion Protein Gene, Curcial for Complete Diagnostic Strategies," Human Mutation, Vol. 7, pp. 280-281 (1996)
	В1	Pan, et al., "Conversion of α -helices into β -sheets features in the formation of the scrapie prion proteins," Proc. Natl. Acad. Sci. USA, Vol. 90, pp. 10962-66 (1993),
	B2	Piccardo, et al., "An Antiserum to Residues 95-108 of Human PrP Detects PrPres in a Variety of Human and Animal Prion Diseases," J. Neuro. Exp. Neurol., Vol. 56, pp. 589 (1997) (abstract only)
	В3	Pirola, et al., "Inhibition of scrapie-associated PrP accumulation. Probing the role of glycoaminoglycans in amyloidogenesis", Molecular Neurobiology, 8:113-120 (1994)
	B4	Prusiner, et al., "Transgentic Studies Implicate Interactions between Homologous PrP Isoforms in Scrapie Prion Replication," Cell, Vol. 63, pp. 673-686 (1990)
	B5	Prusiner, S.B., "Molecular Biology of Prion Diseases," Science, Vol. 252, No. 5012, pp. 1515-1522 (1991)
	B6	Schreuder, et al., "Preclinical test for prion disease," Nature, Vol. 381, pp. 563 (1996)
	B7	Serban, et al., "Rapid detection of Creutzfeldt-Jakob disease and scrapie prion proteins," Neurology, Vol. 40, pp. 110-117 (1990)
	B8	Telling, et al., "Transmission of Creutzfeldt-Jakob disease from humans to transgenic mice expressing chimeric human-mouse prion protein" Proc Natl Acad Sci, Vol. 91, pp. 9936-9940 (1994)
	B9	Telling, et al., "Prion Propagation in Mice Expressing Human and Chimeric PrP Transgenes Implicates the Interaction of Cellular PrP with Another Protein," Cell, Vol. 83, pp. 79-90 (1995)
	B10	Towbin, et al., "Electrophoretic transfer of proteins from polyacrylamide gels to nitrocellulose sheets: Procedure and some applications," Proc. Natl. Acad. Sci., 76(9):4350-4354 (1979)
	B11	Weissmann, "The prion's progress," Nature, Vol. 349, pp. 569-571 (1991)
	B12	Weller, "latrogenic transmission of Creutzfeldt-Jakob disease," Psychol. Med., pp. 1-4 (1989)
	B13	Wells, et al., "The Neuropathology and Epidemiology of Bovine Spongiform Encephalopathy," Brain Pathol., Vol. 5, pp. 91-103 (1995)
	B14	Whittington, et al., "Rescue of Neurophysiological Phenotype seen in PrP null mice by transgene encoding human prion protein," Nat. Gene., Vol. 9, pp. 197-201 (1995)
	B15	Will, et al., "A new variant of Creutzfeldt-Jakob disease in the UK," Lancet, Vol. 347, pp. 921-925 (1996)
	B16	Windl, et al., "Genetic basis of Creutzfeldt-Jakob disease in the United Kingdom: a systematic analysis of predisposing mutations and allelic variation in the PRNP gene" Hum. Genet., Vol. 98, pp. 259-264 (1996)
	B17	Wyatt, et al., "Naturally occurring scrapie-like spongiform encephalopathy in five domestic cats," Vet. Rec., Vol. 129, pp. 233-236 (1991)

EXAMINER DATE CONSIDERED

EXAMINER: Initial if citation is considered, whether or not citation is in conformance with MPEP § 609: Draw Line through citation if not conformance and not considered. Include copy with next communication to applicant.